On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

**755. Adulteration and misbranding of Gilmore's Headache Powders. U. S. v. 45 Packages of Gilmore's Headache Powders. Default decree of condemnation and destruction.** (F. D. C. No. 7354. Sample No. 86370–E.)

This product, in addition to being dangerous to health when used according to directions, failed to bear adequate directions for use and warning statements in the labeling, and contained acetanilid, caffeine citrate, and sodium bicarbonate greatly in excess of the amounts declared on the label.

On April 16, 1942, the United States attorney for the Northern District of Indiana filed a libel against 45 packages of the above-named article at Fort Wayne, Ind., alleging that it had been shipped in interstate commerce on or about November 11 and December 9, 1941, by the Don Gilmore Laboratories, Inc., from Cleveland, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate."

Analysis of a sample of the article showed that each powder contained 6.93 grains of acetanilid, 2.61 grains of caffeine citrate, and 2.50 grains of sodium bicarbonate.

It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess.

It was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Directions: Place a powder on the tongue and swallow with water. Repeat in twenty minutes if necessary," since when taken in accordance with these directions the powders would provide for the administration of slightly less than 14 grains of acetanilid in 20 minutes. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the powders contained acetanilid and the labeling contained no warning that frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug; and, further, that the powders should not be given to children. (3) In that the label failed to bear adequate directions for use. (4) In that the statement on the label, "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate," was false and misleading.

On July 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

## DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[3]

**756. Adulteration of triple distilled water and sterile solution of epinephrine chloride; misbranding of Suppletive Formula No. 1, Sterile Supportive Formula S. G. M. a., Sterile Solution Formula No. 1, Compressed Tablets No. 358, and Compressed Tablets Thyroid; adulteration and misbranding of Neohormestrin, solution of quinine and urea hydrochloride, quinine sulfate tablets, and sterile solution of ovarian extract. U. S. v. E. S. Miller Laboratories, Inc. Plea of nolo contendere. Fine, $75 on each of 4 counts. Imposition of sentence suspended on remaining counts and defendant placed on probation for 1 year.** (F. D. C. No. 4132. Sample Nos. 7368–E, 7397–E, 7655–E, 7939–E, 30843–E, 31909–E, 31912–E, 32631–E, 53828–E to 53831–E. incl., 53833–E, 55734–E.)

This case involved the following violations and products: Failure to bear adequate directions, adequate warning statements, and satisfactory ingredient statements, Suppletive Formula No. 1 and Sterile Solution No. 1; failure to bear adequate directions and warnings, Compressed Tablets No. 358 and Compressed Tablets Thyroid; failure to bear adequate directions and ingredient statements, Sterile Supportive Formula S. G. M. a.; failure to comply with own standard of strength and quality and to bear satisfactory ingredient statement, Neohormestrin; failure to comply with official standard and reduction of quality because of the presence of minute particles of rubber, triple distilled water; failure to comply with official standards of strength and quality, quinine and urea hydrochloride, quinine sulfate, and epinephrine chloride.

[3] See also Nos. 754, 755.